REMARKS

In reply to the Final Office Action issued February 23, 2004, claims 27 and 28 are amended and claim 29 is cancelled.

In the Office Action, the Examiner rejected claims 3-5, 27-29 and 31 under 35 U.S.C. 103(a) for being obvious over Knittel et al taken in view of Joens et al. Knittel et al is relied on for disclosing vaccine compositions comprising inactivated whole cell *L.intracellularis*, or lysates thereof, with an adjuvant, and the use of said vaccines in swine. As acknowledged by the Examiner, Knittel et al do not disclose the *L.intracellularis* ATCC deposit No. 55370.

Joens et al is relied on for disclosing *L.intracellularis*; in particular, ATCC deposit No. 55370. Joens et al is also relied on for disclosing methods for propagating the organism in Henle 407 cells and inoculating the organism into swine to check its pathogenicity. The Examiner also refers to Joens et al for disclosing that the L.intracellularis culture could be used to develop a bacterin using known techniques and that the bacterin could be administered to swine to "permit the pigs to mount an effective immune response against the agent (PPE)."

Relying on this, the Examiner concluded that it would be obvious to use the antigen of Joens et al in vaccine compositions of Knittel et al. The Examiner then stated, "Contrary to Applicant's assertion, the disclosure by Joens et al that said bacterin (immunogen) could be administered to pigs to permit the pigs to mount an effective immune response against the agent (PPE) would provide one of skill in the art not only of a reasonable expectation of success but a motivation to use the disclosed antigen (ATCC No. 55730) as a vaccine."

Rejection over Knettle et al taken with Joens et al is respectfully traversed. The conclusion that the discussion by Joens et al of developing a bacterin using known techniques and administering it to pigs to permit them to mount an effective immune response provided a reasonable expectation of success is wrong and should be withdrawn. There is no disclosure by Joens at el regarding the actual production or use of a vaccine. Joens et al is limited to isolation, characterization and production of the strain deposited as ATCC No. 55730. Which, in view of the difficulty found with growing the organism at the time, was a notable achievement. However, nothing more than conventional methods for producing a vaccine are discussed in the hypothetical. In view of the well known lack of

predictably in the vaccine art, the disclosure of Joens et al provides nothing more than a suggestion to make a vaccine by conventional methods, which fails to provide the reasonable expectation of success necessary to support a conclusion of obviousness. Joens et al can be relied on for nothing beyond the specific deposited strain.

Knittle et al disclose *L.intracellularis* vaccines using both attenuated and killed *L.intracellularis*. These vaccines were made with strain N343, ATCC deposit No. 55783. It is submitted that the success Knittle et al achieved producing vaccines that showed some protection against challenge could not render the strain produced by Joens that resulted in the present application obvious. Again, different strains are expected to yield different results. Thus, success with one strain does not predict success with any other.

With the present amendments, Applicant has also included limitations in the claimed immunogenic composition whereby the *L.intracellularis* antigen component consists essentially of the strain deposited as ATCC deposit No. 55370 that, on administration to swine, induces the production antibodies to specific antigens, which were identified by Western blot. The claims are now limited to immunogenic compositions in which the *L.intracellularis*

antigen must be the specific tissue culture produced, whole cell *L.intracellularis* deposited as ATCC deposit No. 55370.

Even in view of Knittel et al, the possessor of a particular strain of *L.intracellularis* could not predict that the strain could be the basis for successful vaccine. At most, there is the inducement, "obvious to try," which has long been determined not to be sufficient to support a finding of obviousness. Even with Knittle et al before him, and the 55370 strain in hand, the ordinary practitioner would have to undertake to formulate a vaccine, test it and, if necessary, further experiment to attempt to formulate a vaccine providing protection against heterologous challenge. A successful result could not be predicted with assurance.

Major diseases afflicting humans and animals for which there are no effective vaccines available are well known. Furthermore, variants and mutations among disease causing organisms are well known to render previously effective vaccines useless. It is submitted, therefore, until Joens, the present inventor, produced and tested a vaccine using this strain, which he previously isolated and characterized, and showed how to grow, the presently claimed immunogenic composition could not be assured.

The Examiner has also rejected claims 28 and 29 for reciting the "antigen" under 35 U.S.C. 112, second paragraph.

It is respectfully submitted that with the present amendments the basis for the rejection of claims 28 and 29 is overcome.

Applicant respectfully submits that the present amendments introduced to claims 27, to recite "consisting essentially of" in place of "comprising," and to further recite the characteristics of this strain to induce the production of specific antibodies, limit the *L.intracellularis* component to the strain deposited as ATCC deposit No. 55370. The antigen profile was previously considered in the claims and, thus, will require no further searching or additional consideration. Accordingly, it is requested that the Examiner enter these amendments and grant them full consideration.

In view of the above, with the present amendments, it is believed that claims 3-5, 27, 28 and 31 define patentable improvements in the art. Favorable action is solicited.

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